85. What have we learnt? If glyphosate were to become a late lesson we have now ignored the early warnings

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Abstract

The current European Union reapproval procedure for glyphosate is developed as a case study testing whether the 12 precautionary lessons identified by European Environment Agency research as needed to avoid unnecessary harm to society have been incorporated into current regulatory approaches. The working hypothesis that those lessons have not been learnt to a significant degree could not be falsified.

Keywords: precaution, European Union, assessment, herbicide, policies

Introduction

Glyphosate is the active ingredient in the world's best-selling herbicides and is currently available in more than 300 different formulations in Europe alone (Glyphosate Task Force). The European Commission (EC) had been expected to reauthorize glyphosate friction-free until the International Agency for Research on Cancer of the World Health Organization (IARC) classified this herbicide as probably carcinogenic to humans (IARC, 2015).

However, when the European Food Safety Authority, as mandated by law, later published its own conclusions, it stated the herbicide was 'unlikely to pose a carcinogenic hazard to humans' (EFSA, 2015). The EC has already published a proposal to reapprove glyphosate based on EFSA's advice, to be voted on by Member States (Giannopolitis, 2016).

This kind of controversy can be expected but how careful should the political decision be in the face of scientific incoherence? In 2001 the European Environment Agency demonstrated a low precaution level was not in society's interest and derived twelve lessons that should be learnt so history doesn't repeat itself and harm is avoided (EEA, 2001).

The current glyphosate reauthorization procedure will be checked below against each of these lessons (paraphrased in the title of each section below) to determine whether they have been incorporated at all into European thinking, with the underlying hypothesis that no such thing happened – not to a significant degree. If, on the other hand, the learning effectively took place, then it should not be possible to find glaring examples to the contrary.

Lesson 1: deal with unknowns

It is not within the reach of scientists to immediately and fully answer questions as they arise, let alone identify beforehand all questions that need asking. Are there ways of safeguarding against current unknowns that could translate into future risks?

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Glyphosate has been shown to exhibit synergistic behaviour when in the presence of coadjuvants (other chemicals, considered inert by the regulatory authorities) included in the herbicide formulation). Richard *et al*. (2005) showed over ten years ago that Roundup (a commercial glyphosate-based herbicide) was consistently more toxic than glyphosate alone. An Argentinian group (Chaufan *et al.*, 2014), working with agriculturally realistic concentrations, found toxic effects in a glyphosate formulation where none could be found with glyphosate alone.

In its draft renewal text (DG SANTE, 2016) the EC recognises the issue when it mandates that one particular group of coadjuvants (POE-tallowamine, or POE-15) not be used in glyphosate-based herbicides (GBH). However, problems have been shown to occur with other chemicals also present in GBH (Mesnage *et al.*, 2013), and various combinations have not been tested at all (Mesnage *et al.*, 2014), which indicates major data gaps. This illustrates glyphosate's clear potential for future surprises while at the same time hinting at regulatory unwillingness to consider it.

Lesson 2: look for early warnings

Early warnings may take the shape of solitary publications in lesser journals, but they must not be disregarded, particularly if there is no monitoring in place for early detection of unexpected impacts. Such is the case for glyphosate as an endocrine disruptor since the EC has yet to define the necessary official testing criteria (Horel, 2015).

The inability to pinpoint the origin of the endocrine disrupting effects (whether glyphosate itself or coadjuvants) in papers by the Séralini group was enough for the Renewal Assessment Report (RAR) to disqualify the data (Anonymous, 2013). Where research used pure glyphosate, however, such as in Thongprakaisang's work, the disruption detected was reviewed apologetically. In the final listing of peer-reviewed scientific studies on *in vitro* endocrine disrupting effects, 11 out of the 12 publications mentioned are classified as 'not reliable' and 'not relevant' for one reason or another. The remaining paper was considered 'reliable/relevant with restrictions' with the added consideration that 'no conclusion can be drawn that the observed effects are the result of glyphosate exposure.' All 12 articles had detected some sort of negative impact in glyphosate or GBH exposure.

Such a blanket repudiation of peer-reviewed research points to a deliberate prejudgment of any evidence harming an authorisation. The introduction to the RAR states the work overload prevented reviewers from analysing the primary literature, relying instead on the industry's own assessment. This conveys a tainted overtone and is not compatible with a serious determination to find warnings where they might exist.

Lesson 3: react to detected weaknesses

One aspect of the glyphosate controversy is its teratogenicity. A 2012 review (Antoniou *et al.*, 2012) points to such effects after glyphosate or GBH exposure. It also describes how a previous (1998) German assessment report equivocally stated that the regulatory (industry commissioned) studies showed glyphosate did not cause teratogenicity while mentioning increased bone and soft organ anomalies. The studies themselves are not public, but the summaries could be analysed and, still according to the same review, show teratogenic effects at various dosages.

German assessors apparently glossed over the inconvenient (albeit limited) data and no regulatory action ensued. In addition, the 2012 review was ignored during the present renewal procedure. That is the exact opposite of what Lesson 3 should have taught, and shows it remains unlearnt.

Lesson 4: bridge knowledge areas

European regulation 1107/2009 on pesticides requires the EC to address endocrine disruptors and determines such problematic chemicals not be accepted under any dosage. EC's Environment unit (DG ENVI), tasked with defining the appropriate criteria, set up a diverse working group in 2010 comprised of over 40 elements, including representatives from Member States, academic institutions, other DGs, civil society and the industry itself.

Industry, however, lobbied hard until DG SANCO (Health and Consumers, historically more industry-friendly) replaced DG ENVI in 2014 (Horel, 2015). Part of this takeover included the set up by DG SANCO's EFSA, in 2012, of a nine-member endocrine task force. Irrespective of other details, the first composition of this group seems noteworthy. It is particularly relevant only two scientists were appointed, with none of those being a mammalian endocrinologist. Other members included several officials from two countries opposing DG ENVI and the majority in the group had no endocrinology background at all, administrative or otherwise (PAN, 2015).

The contrast between the two DGs couldn't be more suggestive of a learning inversion as regards Lesson 4. The inability, or unwillingness, to be inclusive prevailed in the European process.

Lesson 5: account for real life

It was around the epidemiological studies of glyphosate's cancer causing properties that the current German Renewal Assessment Report, most visibly clashed with the 2B classification (probable human carcinogen) from IARC. The two assessments differed in a number of crucial aspects, as described by Portier *et al.* (2016). Many would be worth exploring but a particular one, the discordant weight attributed to the studies available, is remarkable.

The RAR dismissed on technicalities all case-control studies as not reliable (as opposed to IARC), but valued data from the Agricultural Health Study. This large cohort study (which was also noted by IARC) elicited no cause-effect relationship for glyphosate and non-Hodgkin lymphoma (NHL, a type of blood cancer showing up in the case-control studies as being connected to glyphosate exposure). One problem, however, is the time dimension. In Olsson *et al.* (1988), for example, the average latency period for NHL after exposure to solvents averaged 21 years. In the AHS, on the other hand, the time between exposure and assessment averaged a meagre 6.7 years (Portier *et al.*, 2016). This puts the AHS data in the possible false negative range, largely reducing its validity at this stage: cancers may be yet to arrive. Real life takes time, and the RAR failed to recognise it.

Lesson 6: look into the wider costs and benefits

Pesticides, although defended as a whole by the agrochemical industry, are generally recognised as unsustainable to the point of justifying the introduction of genetically modified food crops as a better option (Klümper and Qaim, 2014). The question is not asked at the assessment and decision-making levels, however, if or when each pesticide's prospective benefits outweigh any potential impacts. Moreover, even if that kind of justification were sought, the analysis would be incomplete. In case there are better options, that attain the same objectives with less or no harm, officials would be hard pressed to approve any pesticide at all. Whether such alternatives do exist for glyphosate is the topic for the next Lesson.

Lesson 7: look for the best alternative

No official focused effort has been carried out to look for alternatives that could pave the way for a glyphosate free future. Nevertheless, the Julius Kühn-Institut, a German federal research agency, did look into the matter (Kehlenbeck *et al.*, 2015) and found that, for the German reality, agricultural and non-professional users alike can adjust to lower glyphosate use, concluding 'glyphosate should not be regarded as a standard measure in arable crop production systems'. This information has not percolated into any EC decision thus far.

Lesson 8: welcome non-experts too

This lesson is a reminder that non-experts and the public, in general, should be enticed to participate and actively heard in technical discussions having a bearing on society, mostly because there is knowledge and perspective to be gained. In glyphosate's case, a public hearing was held by EFSA in 2014. It was, unfortunately, 'entirely unfit for purpose' according to an environmental group that participated (John, 2014). In addition EFSA, according to the same source, eliminated all comments not entirely focused on glyphosate, even though it could have chosen to consider formulations such as Roundup which constitute the vehicle that channel glyphosate into the world. This approach does not bode well for the role of non-experts in European decision making.

Lesson 9: consider the people's feeling

Regarding glyphosate public values can be gleaned through various ways. In 2015 a petition hosted by Avaaz and delivered to DG SANCO contained 1.4 million signatures requesting glyphosate be banned (Neslen, 2015). More recently a Yougov poll of 7,000 Europeans in the five largest Member States evidenced an expressive two third majority in favour of glyphosate's demise (Neslen, 2016). The decision by the European Commission to go ahead with glyphosate's reapproval regardless of public views argues strongly in favour of this Lesson having been ignored.

Lesson 10: stop undue influence

The German RAR was put out by the Bundesinstitut für Risikobewertung (BfR), an official agency reporting to the Federal Ministry of Food and Agriculture. The BfR's 13 member Commission on Plant Protection Products and their Residues includes three experts from either Bayer or BASF, among others multinationals (BfR, 2016). In addition, the BfR report was not signed by the experts who wrote it which, while not corrupt *per se*, is certainly not transparent and opens the door to undue influence.

Lesson 11: the administration could be the problem

The glyphosate RAR summarises industry toxicological studies, but the full documents are not available because of commercial confidentiality (Antoniou *et al.*, 2012). This obstructs evidence cross-examination and has been criticized for years, to the point where DG SANCO has announced it is considering introducing increased transparency (Matthews, 2016). However, until the EC actually changes the rules, the underlying tension will not be solved.

Lesson 12: do not stall

A major example of how Lesson 12 has yet to be learnt is to be found within the European endocrine disruptors proceedings, which intimately intertwine with the glyphosate reapproval timeline.

The 1107/2009 mandate for the definition of endocrine disruptor criteria put the deadline at December 2013. A draft proposal (disparaged by industry) was ready by July 2013 but the EC then made a U-turn and chose to start an impact assessment instead (as demanded by industry), knowing full well this would introduce a three-year delay in the process (Horel, 2015). In March 2014 Sweden (later followed by the European Council and the Parliament) took the EC to court for failure to act and in December 2015 the General Court of the European Union ruled the EC had been illegally stalling (Jacobsen, 2015).

Conclusions

The glyphosate exercise described seems to negatively illustrate every one of the 12 precautionary lessons the European Union should have learnt and, at some level, didn't. As described elsewhere for various other instances (EEA, 2013), scientific data is available, but no early protection measures take place. As the saying goes, to ignore history is to repeat it. Glyphosate is poised to become a late lesson, which would translate into decades of avoidable human suffering and death. A late early warning is hereby served.

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